METHOD FOR PROVIDING CUSTOM FIT THERAPEUTIC FOOTWEAR

This is a Continuation-In-Part (CIP) of my co-pending U.S. Patent Application Serial No.: 09/976,071, which was filed on October 15, 2001 and a Notice of Allowance was issued on September 8, 2003.

Field of the Invention

This invention relates to a method of remotely fitting therapeutic footwear and manufacturing custom molded inserts with accommodations to meet the needs of diabetics and other individuals with a need for custom fit therapeutic shoes and inserts, and to custom fit therapeutic inserts.

BACKGROUND FOR THE INVENTION

Podiatrists and other licensed professional practitioners such as orthotists and pedorthotists have for some years provided therapeutic footwear for diabetics and other patients with a need for custom fitted therapeutic shoes and inserts. However, such practices have often proven unsatisfactory, time consuming and frequently less profitable than desired. The problem is that the practice is time consuming and frequently results in inconsistencies and poorly fitting shoes and inserts, a necessity to replace poorly fitting shoes and more recently to comply with the requirements of Medicare and other health care providers.

It is also common practice for licensed professional practitioners to measure a patient's foot, make a mold of a lower portion of the foot and ask a laboratory or manufacturer to make a custom fit therapeutic insert for placement in a shoe. Such laboratories typically work with a mold of a patient's foot, form a plaster cast from the

mold add or build up material on the plaster cast to provide an indentation when an insert is formed from the cast. In the past, such practices have led to poorly fitting accommodations and less than satisfactory inserts.

It is presently believed that there is a need for and/or a relatively large market for an improved method for providing custom fit therapeutic footwear, i.e. shoes and inserts for diabetic and other patients. There is a need because the improved methods disclosed herein minimize the work of a licensed professional practitioner, result in improved or better fitting shoes and inserts, reduce shoe and insert returns and needs for refitting and provide more accurate accommodations, all at a competitive cost.

BRIEF SUMMARY OF THE INVENTION

In essence, the present invention contemplates a method for manufacturing custom fit therapeutic footwear for diabetic and other patients with a need for custom fit therapeutic shoes and inserts. The method includes the step of measuring a patient's foot and forming an imprint of a patient's foot to identify the patient's footprint and any high pressure areas on the bottom of the foot. The method also includes the step of making a mold of the patient's foot and subsequently making a cast such as a plaster cast of the patient's foot from the mold. A mass of a first insert material, such as a multi-layer sheet of heat moldable polyethylene foam material is provided and formed into a shape that corresponds to the patient's foot as for example by vacuum forming. The insert is then sanded to a smooth finish and to fit the contours of the foot and shoe.

The method also includes the step of providing a mass of a second insert material, preferably a polyurethane material that is softer than the first insert material. The imprint of the patient's foot is then used to position any needed accommodations. For example, the insert is positioned over the first imprint after highlighting those areas to be accommodated with an ink marker. The area to be accommodated is then excavated as for example by abrading or sanding to form a reduced thickness which corresponds to at least one of the high pressure points on a patient's foot. The area of reduced thickness is then partially filled with a softer second insert material to thereby provide a custom molded insert with accommodations.

In a preferred embodiment of the invention, the steps of measuring and imprinting a patient's foot and making a mold of the foot are performed by or under the supervision of a licensed professional practitioner. The forming of a plaster positive cast and insert are then performed at a laboratory which delivers custom fit shoes and inserts to the licensed professional practitioner for dispensing to the patient.

The invention will now be described in connection with the accompanying drawings.

DESCRIPTION OF THE DRAWINGS

Figure 1 is a block diagram which illustrates a first embodiment of the invention;

Figure 2 is a block diagram which illustrates a second embodiment of the invention;

Figure 3 is a block diagram which illustrates another embodiment of the invention;

Figure 4 is a block diagram which illustrates a further embodiment of the invention; and

Figure 5 is a schematic illustration of an insert in accordance with one embodiment of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

The following embodiments of the present invention are designed to make it easy for a podiatrist or other licensed professional practitioner to provide footwear that meets the unique needs of their diabetic patients. They can meet these needs by supplying footwear that treats the lower extremity complications of diabetes. The methods disclosed herein facilitate the work of a podiatrist, improves the outcome of their diabetic patients and at the same time allows much of the work to be done by a technician under the podiatrist's supervision. The method also provides for the manufacture of such items to be done by an outside laboratory or manufacturer of custom inserts. The methods disclosed herein also facilitate qualifying patients, meeting the requirements of Medicare and other health care providers in obtaining better fitting shoes and inserts at a competitive price.

The method in accordance with a first embodiment of the invention will now be described in connection with Figure 1. As shown therein, the step 10 calls for a licensed professional practitioner or their medical technician to measure and make an imprint of a patient's foot and at the same time identify areas of high pressure.

Measuring the patient's foot is normally done with a conventional Brannock device. These measurements should be taken with the patient wearing the socks that they will normally wear with the shoes. Three different measurements are taken: the heel to toe length, heel to ball length (or arch length) and the width. In taking these measurements, it is desirable to use a counter for support. The patient stands with both feet together with the right foot closest to the counter. The Brannock device is placed to the left of the patient's left foot and the patient picks up his left foot and places his left heel on the area of the device that is marked left heel. The feet should be side by side with the heel of the foot placed as far back in the device as possible. Next, the foot is positioned so it is resting against the heel to ball measuring device. There should be no space between the foot and the heel to ball measuring device. The width measuring device is then slid against the outside of the foot (the lateral aspect of the foot.)

While standing in front of the patient, the licensed professional practitioner or technician looks straight down over the foot to obtain the heel to toe length for the longest toe. Viewing at an angle could cause an inaccurate reading. The longest toe is usually the first or second toe but on rare occasions the third toe may be the longest. If the longest toe comes out on the line marked 8, record the heel to toe length as an 8. However, if the heel to toe length measures between a 7 ½ and an 8, record the heel to toe length as 7 ½ plus.

After measuring the heel to toe length, it is necessary to make a heel to ball measurement. With the left foot still in the device, obtain the heel to ball

length by making sure the heel to ball measuring device (arch length measuring device) is next to the widest part of the foot at the ball (i.e. the device is rounded and should encircle the medial aspect of the first met head). This number is recorded.

The width is then measured making sure that the width measuring device is against the outside (lateral aspect) of the foot. The patient is then turned around and positioned so that the Brannock device is to the right side of the patient's right foot and the aforementioned steps are repeated.

After measuring the foot with the Brannock device, the foot is removed from the device. The patient continues to stand with their socks on and the circumference of the widest part of the foot at the ball is measured with a measuring tape. The measurement is made from floor to floor on the medial side of the first met head over the top of the foot and down to the floor on the lateral side of the 5^{th} met head. The technician should make certain that the tape measure is not pulled too tightly against the foot. This measurement is recorded for each foot.

After measuring the foot, a conventional foot imprinter is used to obtain a tracing of the foot and to identify any pressure points on the bottom of the foot. In practice, a conventional foot imprinter is opened and includes a rubber mat having a smooth side and a side with a grid or cross-hatch pattern on it. Several drops of ink are disposed onto the side of the rubber mat that has the grid pattern on it. No ink should be applied to the smooth side of the mat. Thus, the patient will not get any ink on his feet because he will be stepping on the smooth side of

the mat only. Spread the ink with a roller. Press firmly back and forth with the roller until the ink has been spread uniformly over the entire rubber sheet. When finished, the roller is placed on a paper towel. The mat is then re-inked when foot imprints become light.

A piece of legal sized paper is placed in the imprinter on the side next to the rubber mat and the rubber mat is flipped over onto the paper with the smooth side of the mat facing up. The ink side should be facing down on top of the paper. Then, when the patient steps onto the mat, the ink will show up on the paper.

At this point, the patient stands next to the counter for support and faces the technician with their right foot closest to the counter. The foot is placed on the imprinter next to the patient's left foot with the rubber mat of the imprinter next to the left foot. The patient then lifts their left foot and the technician guides it to the center of the rubber mat. With the left foot on the rubber mat, the technician traces an outline of the foot with a blunt object such as a pen with the point retracted. The pen should be held at 90° to the foot and pressed down so that the outline of the foot comes out on the paper underneath the mat. Then, the patient takes a small step forward with the right foot and steps off the mat by lifting their left heel and stepping forward. This procedure is done to obtain a good imprint of any pressure points on the fore foot. The piece of paper from the imprinter is removed and has the footprint and tracing on it. Another blank sheet of legal size paper is then placed in the imprinter and the rubber mat is placed on top of the new piece of paper. The patient is then turned in the opposite direction and the previous steps repeated.

The pressure points indicated on the imprint are then circled for accommodation.

The licensed professional practitioner or their technician also makes a foam impression of the patient's foot in step 12. Impressions are preferably done using a 14 inch foam box. Once again, the patient is asked to stand next to a counter with both feet together with the right foot closest to the counter. The foam impression box is opened and a line marked with a pencil 1 inch from the back edge of the foam on both foam sections. This line mark is used to position the back of the heel.

With the technician standing in front of the patient, the foam box is moved next to the patient's left foot and the patient's left heel is guided onto the 1 inch mark without pressing into the foam. The foot is then held in a neutral position by grasping just below the ankle bone with the technician's thumb and index finger on one hand. At the same time with the other hand apply 2 or 3 fingers on the first metatarsal. While holding the patient's foot in this position, the patient applies downward pressure on the foam material until they meet resistance, the ankle and first metatarsal are held firmly as the impression is being made to avoid tilting of the foot. After the impression has been made and before removing the foot from the foam, the technician firmly pushes down the ends of the toes so that they are not elevated (dorsiflexed). The foot is then removed from the foam, the patient turned in the opposite direction and the foam box is then placed next to right foot and an impression made in the same manner.

The mold imprint and measurements together with the doctor's patient evaluation and foot imprints are then forwarded to the laboratory or manufacturer.

The custom orthotic fabrication process incorporates the impression of the patient's foot from the aforementioned foam block or plastic slipper cast. Once this is received, the fabrication process begins with step 14 by pouring liquid plaster of paris into the impression and waiting for it to harden. Once hardened, the cast is sanded smooth in a manner that is consistent with standard orthotic lab procedures for the fabrication of an accommodative orthotic.

In step 16, a first insert material is provided for example a dual density material consisting of 2 laminated layers of Plastazote material having a thickness of about 5/8" and which is a heat moldable polyethylene foam material or an ethyl vinyl acetate. The top layer is preferably about a 20 durometer medium density Plastazote while the bottom layer or shell is about 35 durometer firm density Plastazote. The medium density top layer of Plastazote material has a thickness of about 1/4 inch and the bottom layer of firm density has a thickness of about 3/8 inch depending on the arch height, heel shape and other factors.

This material which is provided in sheets with 2 layers laminated together is cut to a size that is slightly larger than the foot and placed in a convection oven at 250°F for 2 to 3 minutes until soft. Then the material is placed over the cast which is lying inside a vacuum forming machine with the bottom of the cast (bottom of foot) facing upwards. The vacuum forming machine is closed and the heated material is pulled down over the cast as the air is removed from the vacuum forming chamber to thereby shape the insert material in step 18. The insert is then abraded i.e. ground or sanded to fit the shape and contour of the shoe and foot.

When the insert is completed, a technician trained in making accommodations applies the accommodation that was ordered. The technician uses the ink imprint for positioning the accommodation on the device. The high pressure areas are highlighted on the imprint with a wet ink marker. Then the insert is positioned by lining up the heel cup of the device with the traced outline of the heel on the foot imprint. In step 29, the highlighted area is transferred to the insert by applying pressure to the insert while it is precisely located over the imprint. The area to be accommodated is then excavated or otherwise reduced in thickness as for example using a sanding disc to reduce the thickness of the area of reduced thickness by about 75%. Sanding discs of appropriate size and grit are used. The size or area of the reduced thickness is determined by measuring the diameter of the high pressure areas that are present on the imprint. A second insert material is provided in step 24. Once the selected areas is reduced in thickness the excavation is partially filled in (See step 26) with the second insert material, preferably a sheet of Poron i.e. a 15 durometer polyurethane material that is softer than the Plastazote. The Poron material that is provided is about 1/16 inch in thickness. The final product may then be covered with a third layer or pad of about 1/8 inch 35 durometer firm density Plastazote with an opening therein to surround the area of reduced thickness and finish the device. The insert is then added to or coupled with a shoe and dispensed to a patient in step 27.

The imprint formed in step 10 is also used in shoe sizing. The foot imprint is used to confirm the preliminary size based on the use of the Brannock device. For example, a removable manufactured insole of the preliminary length and width is placed as a template on top

of the foot imprint for comparison. The heel cup of the insert is aligned with the tracing outline of the heel on the imprint. Then a line is drawn around the insert template and compared to the tracing outline on the imprint. It is then determined whether there is adequate length and width to accommodate the foot. An adequate length is determined when the template covers the toes with ½ inch allowance beyond the end of the longest toe. An adequate width is determined by complete coverage of the foot imprint across the ball of the foot. If length and width is inadequate, a series of progressively larger templates are placed over the imprint until a satisfactory match is obtained and the proper size is determined.

As illustrated in Figure 2, the method of providing therapeutic footwear for diabetics and other patients includes an initial step 2. In the initial step the licensed professional practitioner examines the patient's foot for problems and notes problems such as amputation of a part of either foot, foot ulceration, pre-ulcerative callouses, peripheral neuropathy, foot deformity or poor circulation. The method also includes the steps 10 and 12 as described in connection with Figure 1. A step 4 is similar to step 14 but is done by forming a plaster cast and subsequently smoothing the plaster cast as for example by sanding to a smooth finish. Step 6 of the second embodiment of the invention is generally similar to step 16 of the first embodiment of the invention, however, the mass of first insert material is a multilayer laminated sheet of a foam polyethylene. This multilayer sheet of polyethylene foam is then shaped in step 8 by vacuum forming. The insert material is then cut to a size which is larger than the foot and heated in a convection oven at about 250°F for two to three minutes until soft. Then the material is placed on the cast which is placed in a vacuum forming

machine with the bottom of the cast facing upwards. The vacuum forming machine is closed and the heated insert material is pulled down over the cast as the air is removed from the vacuum forming chamber. The insert is then ground to shape to fit the shape and contour of the shoe and last.

After the basic insert is made, the imprint which if prepared in step 10 is used to make any needed accommodations as defined above with respect to the first embodiment of the invention. In a final step 27, the licensed professional practitioner dispenses the shoes to the patient, tests them for fit and completes any insurance forms and other paperwork which is necessary.

In the third embodiment of the invention the procedure follows the general approach of the second embodiment of the invention. However, includes step 33 of patient certification and charting. In order to comply with Medicare and other requirements a statement of a certifying physician as recommended by the durable medical equipment carriers is completed. The third embodiment of the invention also incorporates the step 35 of tracing an outline of a foot on the imprint. Then follows the general procedures from Figure 2 and adds the steps 37 and 39 of providing forms to the licensed professional practitioner as well as training for the practitioners technicians.

The fourth embodiment of the invention incorporates steps 10, 12, 14, 16 and 18 from the first embodiment of the invention.

It then adds the step 40 of providing insoles based on measurements obtained by the podiatrist. The foot imprint is used to confirm the preliminary size in step 42. For example, a removable manufacturer's insole of the

preliminary length and width is placed as a template on top of the foot imprint for comparison. The heel cup of the insert is aligned with the tracing outline of the heel on the imprint. Then a line is drawn around the insert template and compared to the tracing outline on the imprint. It is then determined whether there is adequate length and width to accommodate the foot. An adequate length is determined when the template covers the toes with one-half inch allowance beyond the end of the longest toe. An adequate width is determined by complete coverage of the foot imprint cross the ball of the foot. If the length and width are inadequate a series of progressively larger templates are placed over the imprint until a satisfactory match is obtained and the proper size is determined. Based on the above the appropriate size of the shoe is selected in step 44, the insert added or shipped separately and the shoes and inserts dispensed to the patient.

A further embodiment of the invention contemplates a fitted molded therapeutic insert which meets the needs of diabetics and other individuals with a need for custom fitted therapeutic inserts. The inserts include a multidensity molded base having a shape which corresponds to the bottom of a patient's foot. That base has a length, width and thickness and defines an area of reduced thickness in the base which corresponds to high pressure points on the bottom of a patient's foot. A sheet of plastic insert material which is softer then the molded base at least partially fills the area of reduced thickness. The plastic insert material is essentially the same size as the area of reduced thickness but has a thickness which is preferably less than the thickness of the base. An additional layer or pad of the same material as the base surrounds the area of reduced thickness to provide additional support around a pressure point.

In a preferred form, the insert is made of a multidensity heat moldable material such as polyethylene with a top layer of about 20 durometer hardness and a bottom layer of about 35 durometer hardness. The plastic insert material is made of a polyurethane with a hardness of about 15 durometer while the medium density layer is a polyethylene material with a hardness of about 20 durometers.

A custom fit insert with an accommodation to meet the needs of a diabetic or other individual with a need for therapeutic shoes is illustrated in Figure 5.

As shown therein, a custom fitted molded therapeutic insert 50 includes a molded base 52 which has a shape which corresponds to the bottom of a patient's foot. The base has a length and width to fit the patient's foot and a thickness of about 3/8 inch. The molded base also includes a area of reduced thickness wherein the thickness has been reduced by about 75% and which defines an area which corresponds to a high pressure point on the bottom of the patient's foot.

The base 52 is preferably made of a polyethylene or ethyl vinyl acetate and preferably has a preselected durometer hardness. A plastic insert material such as a sheet 54 having a durometer hardness of less then the base is shaped to fit into the area of reduced thickness and has a thickness of about 1/16 inch. This sheet 54 is preferably made of a foam polyurethane and preferably fits snug within the area of reduced thickness.

As shown in Figure 5, a top layer or pad 56 has an opening that corresponds to the area of reduced thickness and surrounds that area. The pad 56 is preferably of the same material as the base 52, has a thickness of about 1/8

inch and provides additional support for a patient's foot around a pressure point. This pad is fixed to the base material in any conventional manner as for example by adhesive.

While the invention has been described in connection with its accompanying drawings, it should be recognized that changes and modifications may be made therein without departing from the scope of the appended claims.